UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Air Quality Planning and Standards
Research Triangle Park, NC 27711

OFFICE OF
AIR AND RADIATION

SUMMARY OF OAQPS AUDIT FINDINGS

Jacobs Technology, Inc Contract EP-C-15-008, WA3-176

Introduction

This report outlines the findings of the OAQPS audit of WA 3-176 under Contract EP-C-15-008 conducted in May 2019. As a result of the audit findings, OAQPS determined that the data collected for this effort cannot be used due to data quality and integrity issues, and the tests will have to be repeated.

Audit Overview

The focus of the OAQPS audit was on data submitted by Jacobs to OAQPS between February and May of 2019. See Table 1 for the list of data file submissions and corresponding dates.

Table 1. List of data files submitted to OAQPS by Jacobs

No.	Date	Filename	Contents
1	2/13/19	Round_Robin_Fall2018_EPAvsLabs Weights 20190213.xlsx	Data Summaries
2	3/13/19	Round_Robin_Fall2018_EPAvsLabs Weights 20190313.xlsx	
3	3/26/19	OAQPS-RR-2018-Fall Results_KD_20190326.xlsm	
4	4/10/19	Round_Robin_Fall2018_EPAvsLabs Weights 20190410.xlsx	
5	4/10/19	Corrected OAQPS-RR-2018-Fall Results_4-10-19.xlsm	
6	5/17/19	20190517_KD_MasterResults_OAQPS-RR-2018-Fall.xlsm	
7	5/17/19	20190516_KD_Fall 2018 Round Robin Master Raw Data Spreadsheet.xlsm	Raw instrument logs
8	5/17/19	20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx	

The objective of the audit was to assess the analytical results of filter samples collected during November of 2019, the QC results collected during the gravimetric analysis of these filters, and Jacob's adherence to the procedures in SOPs and the project sampling plan.

Examined during the audit were all data submissions from Jacobs, raw data obtained by OAQPS directly from the instrument, and the laboratory notebook maintained by Jacobs. During the audit, several red flags were noted that warranted a closer examination of the data. The OAQPS audit revealed several deficiencies and improper practices, as outlined in the following subsections.

Red Flags

A red flag is an observation that indicates the potential for, or leads the assessor to suspect, system vulnerabilities or improper practices. The following red flags were noted:

1. Data submission 1 (*Round_Robin_Fall2018_EPAvsLabs Weights 20190213.xlsx*) was not in the requested format:
    a. The provided spreadsheet for the required data analysis was not used. Instead, a new spreadsheet was created with the data analyzed in a way that obfuscated issues of comparability between the samples in each test run.
    b. All filter IDs were missing in summary tables, making the data untraceable.
2. Data submission 2 (*Round_Robin_Fall2018_EPAvsLabs Weights 20190313.xlsx*) was still not in the requested format and contained the same issues as Submission 1.
3. Data submission 3 (*OAQPS-RR-2018-Fall Results_KD_20190326.xlsm*) was in the correct format using the required spreadsheet but contained data entry errors so could not be reviewed.
4. Data submission 4 (*Round_Robin_Fall2018_EPAvsLabs Weights 20190410.xlsx*) was not in the requested format.
5. Data submission 5 (*Corrected OAQPS-RR-2018-Fall Results_4-10-19.xlsm*) results showed that the loaded filter RSD's exceed the criterion of 5% for all three test runs (Test 1 = 5.4%, Test 2 = 8.7%, and Test 3 = 16.6%).
    a. OAQPS was not notified that the tests exceeded the 5% acceptance criteria.
6. Data Submission 6 (*20190517_KD_MasterResults_OAQPS-RR-2018-Fall.xlsm*) was submitted with the comment from the contractor that the filter weighing system had mislabeled some samples and the contractor had corrected the filter ID's by looking at the data.
    a. The contractor did not indicate that the results had changed, however the assessor noted that the RSD's changed as follows: Test 2 = 8.1% and Test 3 = 12.7%.
    b. Jacobs posted this different data along with two other files (*20190516_KD_Fall 2018 Round Robin Master Raw Data Spreadsheet.xlsm* and *20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx*) that appeared to be raw data files from the instrument.
    c. Jacobs did not provide an explanation for the different data.
7. No submissions were made of an analysis of the QC data and OAQPS was not notified that any QC data failed the acceptance criteria.
    a. QC checks were found to have been routinely outside of -3 µg< x < 3 µg criteria yet no corrective action was taken.
8. There was no record of any review by a Jacobs Quality Assurance Officer (QAO) of any data.
9. Data were not evaluated by Jacobs for compliance with Sampling Plan or SOP specifications.
10. The project notebook was not maintained.
11. The instrument data acquisition system (DAS) contained the incorrect working mass standard weight values.

Deficiencies

The above red flags led to a closer inspection of the data. OAQPS downloaded all raw data directly from the instrument to perform its assessment. The following are some deficiencies found however, this list is not an exhaustive. Deficiencies are unauthorized deviations from acceptable procedures or practices; a defect in an item; and/or nonconformance with a specification.

1. Many calibration check standard results did not meet the method criteria of ≤±3.1 µg.
    a. The analysis of these standards is required between every ten samples.
    b. The analyst is required to assess the results of these standards for conformance to the criteria and take corrective action if the criteria are not met.
    c. There is no evidence the contractor evaluated the QC results.
    d. OAQPS was not notified that any QC criteria were not met.
2. Filter lab and lot blanks were not analyzed as required by the method.
3. Data were not assessed following analysis.
4. Batch duplicates were not analyzed with each batch as required by the method.
    a. Some were analyzed in subsequent days; however, this is not according to the method.

Improper Practices

The comparison of the raw data OAQPS obtained directly from the instrument against the data submitted by Jacobs revealed numerous improper practices. Improper practices are scientifically unsound or technically unjustified omissions, manipulations, or alterations of procedures or data that bypasses the required QC parameters, making the results appear acceptable; any alteration of data such that the data are unauthentic or untrue representations of the experiment or test performed.

Objective evidence of improper practices was obtained by comparing all data submissions from Jacobs to the raw data OAQPS obtained directly from the instrument. The data assessment was conducted by performing an in-depth review and reconstruction of data from raw source data through the iterations of data submissions from Jacobs. Please reference Table 1 for Submission information. Note that all Tables contain a subset of all data submitted and only include the substituted or manipulated data.

1. In Submissions 1 through 5, data substitution occurred for eight samples from Test 2 and fourteen samples from Test 3. See Table 2.
    a. For seven samples, weigh data collected on 12/4/18 (instrument file *RR Loaded Post1*) was substitited for the weigh data collected on 11/17/18 (instrument file *rr loaded fall1*).
    b. For fifteen samples, weigh data collected on 12/6/18 (instrument file *RR Loaded Post2*) was substituted for the weigh data collected on 11/17/18 (instrument file *rr loaded fall1*).
    c. All other samples were analyzed using the correct data from 11/17/18 (instrument file *rr loaded fall1*).
2. In Submission 6, data for these same samples changed from previous submissions.
    a. These new data were found to be from the original data collected on 11/17/18 (instrument file *rr loaded fall1)*, however they had been manipulated. See Table 3.
3. In Submissions 7 and 8, the "raw data" Jacobs submitted had been altered to correspond with Submission 6.
    a. The raw output from the instrument obtained by OAQPS shows the actual results do not match the altered data or log submitted by Jacobs. See Tables 4 and 5.
4. Samples that are not bracketed by passing QC checks are not valid. Jacobs did not report these failures to EPA or flag any of the data.

a. In the absence of this information, the data were presented to EPA with the presumption of meeting criteria.

Table 2. Substituted Data

Filter ID	Submission Number					Source of substituted data	
	1	2	3	4	5	Instrument File	Weigh Date
	Average mg						
T8636045	366.6294	366.6294	366.6294	366.6294	366.6294	RR Loaded Post1	12/4/2018
T8636046	371.1428	371.1428	371.1428	371.1428	371.1428		
T8636047	379.3186	379.3186	379.3186	379.3186	379.3186		
T8636048	376.8228	376.8228	376.8228	376.8228	376.8228		
T8636049	380.1596	380.1596	380.1596	380.1596	380.1596		
T8636050	376.4000	376.4000	376.4000	376.4000	376.4000		
T8636051	372.5979	372.5979	372.5979	372.5979	372.5979		
T8636052	372.6765	372.6765	372.6765	372.6765	372.6765	RR Loaded Post2	12/6/2018
T8636065	372.1528	372.1528	372.1528	372.1528	372.1528		
T8636068	367.9004	367.9004	367.9004	367.9004	367.9004		
T8636069	368.6519	368.6519	368.6519	368.6519	368.6519		
T8636070	369.0473	369.0473	369.0473	369.0473	369.0473		
T8636071	369.2411	369.2411	369.2411	369.2411	369.2411		
T8636072	372.2397	372.2397	372.2397	372.2397	372.2397		
T8636073	366.4253	366.4253	366.4253	366.4253	366.4253		
T8636074	368.5178	368.5178	368.5178	368.5178	368.5178		
T8636075	369.5482	369.5482	369.5482	369.5482	369.5482		
T8636076	374.4564	374.4564	374.4564	374.4564	374.4564		
T8636077	391.9989	391.9989	391.9989	391.9989	391.9989		
T8636078	368.4124	368.4124	368.4124	368.4124	368.4124		
T8636079	386.8380	386.8380	386.8380	386.8380	386.8380		
T8636080	365.3188	365.3188	365.3188	365.3188	365.3188		

Note the source of the data should have been from instrument file “rr loaded fall1” collected on 11/17/18

Table 3. Manipulated Data

Submission 6		
Reported Filter ID	Average mg	Actual Filter ID Associated with Reported Data
T8636045	366.6485	T8636049
T8636046	371.1562	T8636050
T8636047	379.3355	T8636051
T8636048	376.8376	T8636052
T8636049	380.1814	T8636045
T8636050	376.4213	T8636046
T8636051	372.6187	T8636047
T8636052	372.7015	T8636048
T8636065	372.1622	T8636073
T8636068	367.9169	T8636076
T8636069	368.6747	T8636077
T8636070	369.0608	T8636078
T8636071	369.2566	T8636079
T8636072	372.2545	T8636080
T8636073	366.4282	T8636065
T8636074	368.5257	T8636144
T8636075	369.6137	T8636145
T8636076	374.4681	T8636068
T8636077	392.0179	T8636069
T8636078	368.4180	T8636070
T8636079	386.8639	T8636071
T8636080	365.3322	T8636072

Table 4. Summary of Raw Data Obtained Directly from Instrument by OAQPS

Raw data pulled directly from instrument by OAQPS												
Filter ID	instrument file "rr loaded fall 1" (weighed 11/17/18)				instrument file "RR Loaded Post1" (weighed 12/04/18)				instrument file "RR Loaded Post2" (weighed 12/06/18)			
	Weigh 1	Weigh 2	Weigh 3	Avg	Weigh 1	Weigh 2	Weigh 3	Avg	Weigh 1	Weigh 2	Weigh 3	Avg
T8636045	380.1815	380.1803	380.1824	380.1814	366.6315	366.6297	366.6269	366.6294				
T8636046	376.4203	376.4220	376.4215	376.4213	371.1449	371.1414	371.1420	371.1428				
T8636047	372.6197	372.6189	372.6176	372.6187	379.3182	379.3203	379.3174	379.3186				
T8636048	372.7006	372.7047	372.6993	372.7015	376.8218	376.8266	376.8200	376.8228				
T8636049	366.6504	366.6487	366.6463	366.6485	380.1562	380.1628	380.1597	380.1596				
T8636050	371.1556	371.1565	371.1564	371.1562	376.3980	376.4038	376.3983	376.4000				
T8636051	379.3345	379.3377	379.3343	379.3355	372.5942	372.5979	372.6017	372.5979				
T8636052	376.8387	376.8379	376.8362	376.8376					372.6788	372.6716	372.6791	372.6765
T8636065	366.4301	366.4284	366.4261	366.4282					372.1493	372.1578	372.1512	372.1528
T8636068	374.4689	374.4669	374.4686	374.4681					367.8994	367.9030	367.8988	367.9004
T8636069	392.0186	392.0180	392.0172	392.0179					368.6534	368.6529	368.6495	368.6519
T8636070	368.4156	368.4198	368.4186	368.4180					369.0500	369.0447	369.0471	369.0473
T8636071	386.8645	386.8637	386.8636	386.8639					369.2410	369.2388	369.2434	369.2411
T8636072	365.3322	365.3321	365.3323	365.3322					372.2399	372.2363	372.2430	372.2397
T8636073	372.1630	372.1625	372.1611	372.1622					366.4256	366.4242	366.4262	366.4253
T8636074	365.5474	365.5482	365.5493	365.5483					368.5158	368.5200	368.5175	368.5178
T8636075	368.7034	368.7072	368.7073	368.7060					369.5473	369.5515	369.5458	369.5482
T8636076	367.9195	367.9174	367.9139	367.9169					374.4577	374.4581	374.4535	374.4564
T8636077	368.6748	368.6748	368.6746	368.6747					391.9998	391.9957	392.0011	391.9989
T8636078	369.0597	369.0601	369.0626	369.0608					368.4117	368.4104	368.4150	368.4124
T8636079	369.2563	369.2561	369.2575	369.2566					386.8400	386.8357	386.8384	386.8380
T8636080	372.2535	372.2545	372.2555	372.2545					365.3201	365.3149	365.3214	365.3188

Table 5. Manipulated Data Submitted to OAQPS as Raw Data by Jacobs

Jacobs Reported Filter ID	Actual Filter ID	Data submitted as "Raw" from Jacobs							
		Submission 6				Submission 7			
		Weigh 1	Weigh 2	Weigh 3	Avg	Weigh 1	Weigh 2	Weigh 3	Avg
T8636045	T8636049	366.6504	366.6487	366.6463	366.6485	366.6504	366.6487	366.6463	366.6485
T8636046	T8636050	371.1556	371.1565	371.1564	371.1562	371.1556	371.1565	371.1564	371.1562
T8636047	T8636051	379.3345	379.3377	379.3343	379.3355	379.3345	379.3377	379.3343	379.3355
T8636048	T8636052	376.8387	376.8379	376.8362	376.8376	376.8387	376.8379	376.8362	376.8376
T8636049	T8636045	380.1815	380.1803	380.1824	380.1814	380.1815	380.1803	380.1824	380.1814
T8636050	T8636046	376.4203	376.422	376.4215	376.4213	376.4203	376.422	376.4215	376.4213
T8636051	T8636047	372.6197	372.6189	372.6176	372.6187	372.6197	372.6189	372.6176	372.6187
T8636052	T8636048	372.7006	372.7047	372.6993	372.7015	372.7006	372.7047	372.6993	372.7015
T8636065	T8636073	372.163	372.1625	372.1611	372.1622	372.163	372.1625	372.1611	372.1622
T8636068	T8636076	367.9195	367.9174	367.9139	367.9169	367.9195	367.9174	367.9139	367.9169
T8636069	T8636077	368.6748	368.6748	368.6746	368.6747	368.6748	368.6748	368.6746	368.6747
T8636070	T8636078	369.0597	369.0601	369.0626	369.0608	369.0597	369.0601	369.0626	369.0608
T8636071	T8636079	369.2563	369.2561	369.2575	369.2566	369.2563	369.2561	369.2575	369.2566
T8636072	T8636080	372.2535	372.2545	372.2555	372.2545	372.2535	372.2545	372.2555	372.2545
T8636073	T8636065	366.4301	366.4284	366.4261	366.4282	366.4301	366.4284	366.4261	366.4282
T8636074	T8636144	368.5239	368.5297	368.5236	368.5257	368.5239	368.5297	368.5236	368.5257
T8636075	T8636145	369.6142	369.6144	369.6124	369.6137	369.6142	369.6144	369.6124	369.6137
T8636076	T8636068	374.4689	374.4669	374.4686	374.4681	374.4689	374.4669	374.4686	374.4681
T8636077	T8636069	392.0186	392.018	392.0172	392.0179	392.0186	392.018	392.0172	392.0179
T8636078	T8636070	368.4156	368.4198	368.4186	368.4180	368.4156	368.4198	368.4186	368.4180
T8636079	T8636071	386.8645	386.8637	386.8636	386.8639	386.8645	386.8637	386.8636	386.8639
T8636080	T8636072	365.3322	365.3321	365.3323	365.3322	365.3322	365.3321	365.3323	365.3322

Summary of OAQPS Findings

Based upon the information gathered, an apparent sequence of events emerged as follows:

1. A subset of filters weighed on November 17, 2018 were misidentified by the contractor in the instrument DAS or in the robotic carrier.
2. Because the contractor did not review sample or QC data after each weigh session, the error was not discovered by the contractor until sometime in February of 2019 when he began to summarize the data.
3. EPA was not notified of the sample ID mix-up. Instead, the contractor substituted data from two other weigh sessions for these samples and submitted these data to EPA on five separate occasions.
4. In the final data submission, the contractor submitted the original data collected on November 17, 2018, but arranged the data to obtain what appeared to be valid results. For two of these filters, the contractor substituted data from filters that were not used in the study.
5. The contractor altered the run logs from the instrument in a spreadsheet and submitted them to EPA with the final data labeled as "Raw" data. Had EPA used these run logs to review the final submission, the data in the summary would have appeared valid.

OAQPS stopped their review after identifying these serious issues and requested an independent audit of the data and project by ORD QA personnel. Two audits were performed by ORD, both of which produced findings consistent with OAQPS audit.